

Here is the link to the Wiki page:

<http://spl-work-group.wikispaces.com/>

### **Topics/Questions for Discussion for SPL ER/DL Process Team – 15-Nov-17**

**Blanket No Change Certification for Product Listing SPL document type has been enabled in production in CDER Direct: <https://direct.fda.gov>**

Vendors and conversion houses are now equipped with No Change Certification Software. **There will be no extensions granted for the Blanket No Change Certification Deadline.** If you have products that have been updated during the year they are already certified.

### **Certified Product Lookup Available**

FDA added the column to the NDC Directory in the downloadable files, but the date does not appear in the search (just yet). A new column has been added to the existing NDC Directory files that can be used to determine if the product has been certified.

#### **New column definition:**

**Listing\_Record\_Certified\_Through\_Text/String** This is the date when the listing record will expire if not updated or certified by the firm.

If the date is 12/31/2018 the product has been certified this year and if the date is 12/31/2017 the product has not been certified for this year.

**Data Files for Unfinished Drugs:** [https://www.accessdata.fda.gov/cder/ndc\\_unfinished.zip](https://www.accessdata.fda.gov/cder/ndc_unfinished.zip)

**NDC Database File for listed drugs:** the Excel version is

<https://www.accessdata.fda.gov/cder/ndcxls.zip>

Text version is <https://www.accessdata.fda.gov/cder/ndctext.zip>

1. If someone needs to be added to the email list, please have them reach out to both:
  1. Benjamin.E.Harpster@gsk.com
  2. Herbert.Obrien@bayer.com
2. Marcia Howard shared her correspondence with Leyla Rahjou-Esfandiary regarding the use of CDER direct for NDC reservation.
  3. Currently, the plan is that it will be in place by the end of November. [As of 12/9/2017, there is nothing posted for CDER Direct.](#)
3. **From Susan Crane:** I tried to do a NO CHANGES CERTIFICATION for one of my clients, a private label distributor. When I added the Registered Establishment (which I didn't realize was going to be a requirement) and tried to pull up the products, none of those with the PLD's labeler code show up, even though I know they are all currently listed products. Do they all have to be added manually? Why does this happen? I'm wondering if maybe the manufacturer hasn't listed the product under its own labeler code as "manufactured exclusively for a private label distributor" it does not come up? [If your original files are not created in CDER Direct not all functions are available and manual input may be required. CDER Direct will populate a number of things but not everything. Distribution drug listings which reference an NDA, Monograph and BLA they all appear to populate](#)

but something that has been manufactured for private label or drugs for further processing they don't seem to populate on their own. This question should be sent to Paul and Leyla.

Also, another consultant told me that their contact at the FDA told him that the Authorized Agent CAN be the consultant (which conflicts with my notes from one of our meetings a few weeks ago). Can you confirm WHO can/should act as the Authorized Agent? [The Authorized Agent is the registrant or PLD or actual person who is submitting the certification, a consultant can be assigned as the Authorized Agent.](#)

Demonstration of an actual recertification submission (going to try and show both CDER direct and the software that I use).

CDER Direct – Please note that this is the first time we are using this BNCCC program and this is our experience, any problems or questions you have can be answered by contacting eDRLS. If you need the Annual Certification of Drug Product Listings from the recent Labeling program, it can be found on the wiki, or contact Herb or Ben and we will provide.

- Authorized Agent Details are the same as the account holder or this can be manually inserted with a different authorized agent
- This will pull up information linked to that entity and bring in a number of labeler codes
- Labeler codes can be added in manually
- Choose a labeler Code
- Choose an establishment and product code for this to work
- Initially I thought if you put in the labeler code it would populate everything and you were done, that is not the case
- When you select the labeler code you end up with every entity that is performing an operation in those drug listings. If you cover the full supply chain in your listings you will come up with API, Manufacturer, Labeling, Packager and not just the manufacturing information. You are getting more information than you were expecting.
- For this demo we'll choose one manufacturer but remember when you show products it will show every product associated with that manufacturer and not just your products.
- You will have to select the products you want.
- A box on in the left column tells you the products has not been certified



-	12866-5114	Avved	-	09-DEC-17	INJECTION	TESTOSTERONE UNDECAN+	Current		-
<input type="checkbox"/>	43624-001	Valstar	-	01-MAY-15	SOLUTION, CONCENTRATE	VALRUBICIN (40 mg/1 +	Pending		-
-	436		-	25-APR-17	INJECTION	ERIBULIN MESYLATE (+	Current		-

- You can view the status:
  - Certified: This Product has already been certified for the current year.
  - Pending: This product has not been certified yet.
  - Pending Compliance Case: There is a compliance case pending and this product cannot be certified.
  - Expired/Completed: This product has passed its marketing end date and cannot be certified.

- Current: A new version has been received this year and the Product does not need to be certified.
- If you're product has is still pending the last lot and expiration date but the product is no longer in production, it needs to be recertified until every year until the marketing end date. *LuAnn M*
- When the last lot and expiry is in the future, because your file is marked as complete and you are including the last lot you don't need to certify because they are already completed. *Kate D*
- Expired completed files are no longer on the DailyMed
- If marketing status is complete and you have end dates you should not be able to certify the product. You will get a validation error if you include it.
- If the expiration date has not passed, it is left as pending in case you want to update it this year. The only way to update is with a full label submission. The implementation guide will not let you include it in a BNCC. You could resubmit the full SPL and make the marketing status active and that will be the current submission that is certified.
- The implementation guide states that the status has to be active to be certified.
- If you have a large number of products, you can submit multiple BNCC documents with different setids and they can be sent in incrementally. Products submitted previously will show as certified.
- Everytime you choose a site it will list every product code that is made there, not just yours.
- Bulk listings are not populating automatically in CDER Direct.
- The Filter under actions can be used to just pull your NDCS. *LuAnn Mays*

a. Click on checkbox next to establishment

ESTABLISHMENTS

SHOW PRODUCTS

ADD ESTABLISHMENT

**Note:** Establishments whose drug listing files are certified for.

\* The list below only contains those establishments associated with the labeler that have not been indicated to be of confidential relationship. To add establishments that may have been previously indicated as confidential, please use the Add Establishment button. If the establishment was submitted using this CDER Direct account, the confidential establishment will be included.

\* Use check box in the report header for "Select All" functionality.

Rows 15

<input type="checkbox"/>	DUNS	NAME	PHYSICAL ADDRESS	CONTACT DETAILS	DELETE
<input type="checkbox"/>	143696495	Sharp Corporation	7451 Keebler Way, Allentown, PA, 18106, USA	Barbara H. Ost, 1-610-366-8748, barbara.ost@sharpservices.com	
<input checked="" type="checkbox"/>	315015962	Bayer Pharma AG	Muellerstrasse 170-178, Berlin, , 13353, DEU	Herbert O'Brien, 862-404-3595, herbert.obrien@bayer.com	
<input type="checkbox"/>	323033480	Bayer Pharma AG	Ernst-Schering Strasse 14, Bergkamen, , 59192, DEU	Herbert O'Brien, 862-404-3595, herbert.obrien@bayer.com	

b. Click on Show Products

Reports 1. Herb O'Brien
Rows 15

Saved Report = "Herb O'Brien"

<input type="checkbox"/>	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	VIEW SPL	DELETE
-	0024-5820	Oforta	31-DEC-11	07-JUL-15	TABLET, FILM COATED	FLUDARABINE PHOSPHAT+	Expired/Completed		-
-	0062-1411	Ortho Micronor	01-NOV-13	27-MAY-14	TABLET	NORETHINDRONE (.35 m+	Expired/Completed		-
-	0093-5423	Gianvi	-	25-SEP-17	KIT	-	Certified		-
-	0430-3754	ESTRACE	-	11-MAY-17	CREAM	ESTRADIOL (.1 mg/1 g+	Current		-
-	0555-9131	OCELLA	-	02-OCT-17	KIT	-	Certified		-
-	0781-4075	Drosiprenone/Ethinyl Estradiol/Levomefolate Calcium and Levomefolate Calcium	-	18-OCT-16	KIT	-	Certified		-
-	0781-4103	Drosiprenone/Ethinyl Estradiol/Levomefolate Calcium and Levomefolate Calcium	-	02-OCT-17	KIT	-	Certified		-

4. Under actions, click on filter

**GO** Reports 1. Herb OBrien Rows 15 **ACTIONS**

**Filter**

Filter Type ☒ Column ☐ Row

Column	Operator	Expression
PRODUCT NDC	=	0430-3754

d. Select product NDC and it will filter out the NDCs that are not associated with your product code.

[Saved Report = "Herb OBrien"](#)  
[PRODUCT NDC = '0430-3754'](#)

	PRODUCT NDC	PROPRIETARY NAME	MARKETING END DATE	LOAD DATE	DOSAGE FORM NAME	ACTIVE INGREDIENTS	STATUS	VIEW SPL	DELETE
-	0430-3754	ESTRACE	-	11-MAY-17	CREAM	ESTRADIOL (.1 mg/1 g)	Current		-

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- When you select all, you would think that it would just select, you would expect it to select only your filter but it will select the hidden one's as well. This needs to be pointed out
- Is there a way to get a receiver acknowledgement like when something is submitted in the gateway? You will see the status of your submission in the STATUS window to the left.

<a href="#">SUBMISSION ACCEPTED</a>	5c4b8956-e379-ffdd-e053-2a91aa0aed0d	5c4b8956-e37a-ffdd-e053-2a91aa0aed0d	cd5942681037.6402785139@direct	1	BLANKET NO CHANGES CERTIFICATION OF PRODUCT LISTING	Herbert O'Brien	08-NOV-2017 16:30:27	-
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- You can download your file under actions:

**GO** Rows 15 **ACTIONS**

**Download**

Choose report download format:

## Vendor Software

Please note that this is not an endorsement of any vendor. There are numerous vendors represented in this group as well as conversion houses. We can provide that information, if you would need their help.

4. From Tricia Pasek: Has anyone else had significant delays in responses for manual override requests? Paul Tenaglia from Apotex has said they have had problems with it.

There have been some significant delays in manual override requests. It has been very busy with all of the SPL developments. If something is ABSOLUTELY URGENT, put that in your subject line but please do not use this unless it is a last case priority. First of all try to resolve multiple validation failures. Do not request an override for one issue, when there are multiple reasons the file has failed validation. Keep your explanation concise, no need to include the failure notice. Put the CI number in the subject with manual override request. Lonnie is now on top of it and is catching up on requests. The ideal thing is to get your submissions in early and leave room for a delay in any manual override request. The FDA expects a backlog so get your submission in before December 15. Remember a manual override is compared word for word. There will be a process in place to ensure that the FDA addresses any manual overrides submitted before Dec 31.

Ben will send out some simple directions on the proper way to request an override.

Nadine Lewis of Astrazeneca: When it is appropriate to use a different NDC (package code) on an inner layer label (i.e., device, vial, bottle or packet), from the outer container label. I understand that a “kit” must have different NDCs.

Lastly, are CBER and CDER now aligned on this?

For CBER, there has to be a different packaging code for every level, for CDER it is for saleable units and also if you want to use the same part in multiple presentations (for example the same diluent syringe). CDER and CBER are not aligned.

5. When you have the same product going into different kits and the kits are different sizes and you submit 2 different SPL documents, the product code NDC must be different. This is not clear in the regulations. You find out the hard way when you get a validation error. The way the regulations are written the product code is describing a drug product with a certain strength and certain characteristics what the FDA is doing is applying that to a kit. You can't use the same product code for a drug that you do on a kit because they are 2 different products. If you are talking about 2 different kits they cannot share the same product code which is not spelled out in the regulations the FDA is applying the concept of a product. A product would imply a certain combination of drug products and if the combinations are different then you can't use the same product code. For example a multi-level packaging for a kit the kit is in a box and the box is in a carton it should be possible to use the same product code. The product code describes a particular type of kit with certain drug products in it.
6. If you have a product that you sell under an NDC number, a stand alone product then that product is packaged with another drug in a kit configuration in an SPL file, you have the same NDC that you're selling as a stand alone product in a kit in a separate SPL file. If you add the stand alone product to a kit, that part needs to match exactly what was in the stand alone product.
7. Amanda Broughton (Jubilant Hollister) - Will DailyMed be updated with a new date after the Recertification No Change has been completed? For CMO's who are ultimately responsible, I was hoping there is a public record to verify that PLD's have actually done their part (we have contracts in place indicating that our clients are responsible for their drug listing).

Not at this time, the BNCC will be separate from the DailyMed. The BNCC cannot be used to end the marketing of a product, that will still need to be done in the CoL SPL. The BNCC is not linking to the

setid and will not update the DailyMed.

If a company wants proof of recertification, they can request the other party to provide the submission document as proof it was certified.

8. Frances Change of Amgen:

We have a prefilled cartridge (containing drug product) that is meant to be used together with a device (does not contain any drug). The device is meant to hold the prefilled cartridge in place for injection of the drug.

The prefilled cartridge and device are packaged separately (not in a kit together). It is my understanding that devices alone without drug product, should not be drug-listed on a SPL file.

However, I would like to get more clarity on combination drug/device products.

Can the team kindly advise:

- a. Does the device need to be also drug-listed if it is meant to be used together to deliver the drug product?
- b. If so, how can I list it? Using "as Part of Assembly" data element? (screenshot below from the current FDA Guidance document "Structured Product Labeling Implementation Guide with Validation Procedures v1.0", Revision 201710130913)

**Products sold separately but meant to be used together:** when products are used together but packaged separately, the data element <asPartOfAssembly> is used to identify the other product. The products could be drugs or devices.

- c. How do other companies handle similar situations? *To be carried over*

9. Sandra Kuhn – Janssen

10. We have a product that has three different formulations included in one SPL. We have withdrawn the NDA for one of the formulations and updated the market end date. Once the product is delisted, do companies remove the principle display panel from the SPL or does it continue to be included in the SPL.

I don't remove anything from the SPL until the last lot expiry has passed for the discontinued sku(s). Once that date has passed, on the next update I will remove whatever I can. In the above scenario, I would remove the applicable PDP, the applicable Product Data Elements info, and any reference to the product code in the Labeler/Manu section. How supplied would also be updated.

11. Amanda Broughton – Jubilant HolisterStier How do you find out the registrant information for a product you make for another company where their drug listing has that information confidential? Contact the company you are making the drug for and find out what they want to use. If they won't provide it, then I would either enter the labeler info or leave it blank. Anyone have another suggestion?